HQ U.S. Air Force Academy

Integrity - Service - Excellence

USAFA Institutional Review Board (IRB)

Requirements for Informed Consent Document (ICD) Revie

HQ USAFA/XPR

Historical Basis for Formalized Informed Consent (IC)

- Nazi “experiments” on concentration inmates
- Hidden taping of jury deliberations
- Thalidomide testing
- Injection of live cancer cells in patients
- Milgram obedience studies
- Alabama syphilis studies

Informed Consent

- One of the primary ethical requirements underpinning human subjects research
  - Assures that subjects understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate
- Protects the autonomy of the subject and limits legal hazards to researcher

10 Elements to Informed Consent

- Description of study
  - Purpose, duration, procedures, compensation/costs
- Description of risks
  - Reasonably foreseeable risks, discomforts
- Description of benefits
  - Direct benefits to subject
- Disclosure of alternatives
  - Same benefits/treatments available elsewhere?

10 Elements (continued)

- **Extent of confidentiality**
  - **How will data be protected**
- **Risks/Inconveniences**
  - **Describes the risks/inconveniences involved with participating**
- **Compensation or treatment for injury**
  - **Only for studies with greater than min. risk**
- **Unanticipated Adverse Events**
  - **Who to contact incase of an event**

10 Elements (continued)

- **Contact for questions**
  - **research, subject rights, research injury**
- **Voluntary participation statement**
  - **Can withdraw at any time w/o loss of benefits**

Content Vs. Adequacy of ICD

- **Content: Are 10 basic elements addressed?**
- **Adequacy: Are they understandable from the subject's perspective?**
  - **How would you react if you were a subject being asked to participate in the study?**
  - **Each IRB member brings the perspective from their representational capacity**

Common ICD Pitfalls

- Failure to include all required elements or omission of important information
- Use of technical jargon
- Failure to state requirement to report violation of law
- Failure to notify disclosure of information beyond research team
- Exculpatory language to waive legal rights or release researcher from liability for negligence
- Failure to consider the legal age of consent

Informed Consent as Process

- **Informed consent is an ongoing process, NOT a one-time occurrence**
  - **Is there any important new information that might impact willingness to participate?**
  - **Are impediments to free choice removed?**
    - **Especially the manner, timing, place and personnel involved with maintaining consent**
  - **Are there safeguards for vulnerable populations?**

Cadets as a Vulnerable Population

- **Cadets present a “doubly” vulnerable research population; subject to undue influence in their role as:**
  - **Student**
    - **student-teacher relationship, grades, competitive selection**
  - **Military member**
    - **Social hierarchy of military, upperclass-underclass influences, cadet-officer influences, class loyalty**

ICD Documentation

- ICD is required for all nonexempt, DoD supported research
- ICD documents voluntary participation
  - Copy shall be provided to subject
  - ICD must be kept forever, they are a legal document
- IRB may decide to implement principles of informed consent even for exempt research
  - Voluntary participation, purpose of research, uses of information, etc.

Special Issues in Informed Consent

- **Some situations require careful IRB consideration regarding invasion of privacy**
  - **Blanket record reviews**
  - **Observations of behavior**
  - **Deception or incomplete disclosure**
  - **Placeboes and randomization of treatments**
  - **Exempt research involving sensitive topics**
    - **sexual behavior, ethical behavior, drug/alcohol use, etc.**

Summary

- **IC is a primary ethical underpinning to human subjects protection**
- **IRB reviews IC according to 10 required elements & adequacy**
- **IC is an ongoing process**
- **Cadets are a “doubly” vulnerable population**
- **IC required for all nonexempt, DoD research**